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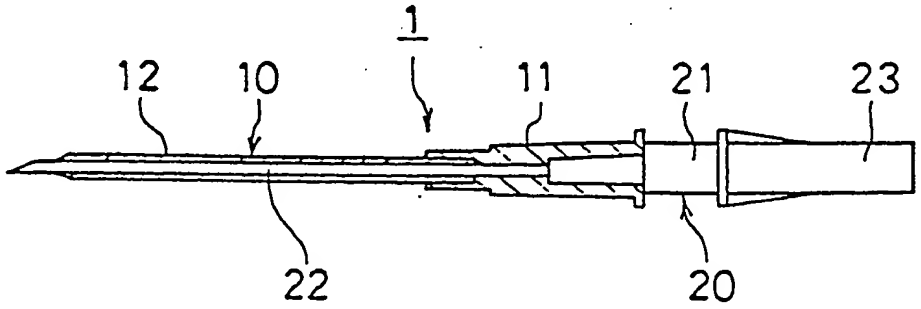
(54) Indwelling catheter.

(57) The present invention is the indwelling catheter which is inserted into a blood vessel, and is made of a material having a Shore D hardness of 50 through 70, and an impact resilience of 40% or more. The material of said catheter is a polyester elastomer having a hard segment comprising an aromatic crystalline polyester and an elastic segment comprising an aliphatic polyester or an aliphatic polyether.

Fig. 1



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material is Shore D of over 50, thereby ensuring the firmness required for a catheter. Namely, an excellent inserting operability can be ensured.

(2) If the impact resilience of a catheter material is less than 40 %, a catheter will be easily plastically deformed, with its recovery reduced, and it is further easily given a bend kink. According to the present invention, namely, the impact resilience of a catheter material is over 40 % and it is satisfied, and a catheter hardly be, therefore, given any bend kink, and can smoothly follow the bend of a region where it will be indwelt, caused by the motion of an arm in its indwelling into a blood vessel. Namely, an excellent indwelling satability can be ensured.

(3) Since the impact resilience of a catheter material is satisfied as mentioned in the above item (2), a catheter hardly be given any bend kink and the bend kink given to the catheter in the indwelling stage can be immediately straightened, when it is removed from a blood vessel, and as a result, the catheter can be smoothly removed therefrom. Namely, an excellent removing operability can be ensured.

(4) Since the hardness of a catheter material is Shore D of below 70 and it is sufficiently flexible, only a small stimulation will be given on a blood vessel wall, when a catheter is indwelt into a blood vessel, so that any damage of the blood vessel wall or phlebitis may not be caused. Namely, an excellent biocompatibility iy can be ensured.

According to the invention described in claim 2, 3 and 4, the following effects (5), (6) and (7) will be obtained.

(5) Since a catheter material is polyester elastomer, the anti-kink property of a catheter is satisfied and the catheter may not be, therefore, broken when it is inserted into a blood vessel. Namely, an excellent inserting operability can be ensured.

(6) Since the anti-kink property of a catheter material is satisfied as mentioned in the above item (5), a catheter may not be broken, even by the strong bend of a region where it will be indwelt, caused by the motion of an arm in its indwelling into a blood vessel. Namely, an excellent indwelling stability can be ensured.

(7) Since a catheter material is polyester elastomer, the catheter exhibit a better anti-thrombus property, and has further a "biocompatibly" indwelling stability.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic view showing an indwelling catheter assembly, to which the present invention is applied ; and

Fig. 2 is a schematic view showing the recovery test of an indwelling catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An indwelling catheter assembly 1 is assembled by incorporating a puncture needle 20 into an indwelling catheter 10.

The indwelling catheter 10 is made up by bonding a catheter 12 to a hub 11. The puncture needle 20 is made up by bonding a hollow stainless needle 22 to a hub 21. The hub 21 of the puncture needle 20 has a filter 23 put thereon.

The indwelling catheter 10 is introduced into a blood vessel in the state of being incorporated with the puncture needle 20. After the introduction of the indwelling catheter 10 into the blood vessel is confirmed by virtue of the coloration of the filter 23 due to blood, the puncture needle 20 is separated for removal therefrom, and an infusion tube will be connected to the hub 11. Thus, the indwelling catheter 10 is indwelt in such a state that the catheter 12 is further introduced into the blood vessel, and then removed from the blood vessel, after it is used for infusion for a given period of time.

The catheter 12 of the indwelling catheter 10 is, indeed, made of a material having a Shore D hardness of 50 through 70 and an impact resilience of 40% or more.

In the present invention, polyester elastomers are used as a polymer meterial for said catheter 12, because these polymers have a proper biocompatibility as well as the abovementioned hardness and impact resilience.

Polyester elastomers are of block copolymers in which the chemically structural hard segment comprises a polyester component. In general, an aromatic crystalline polyester compnent is used for the hard segment. Polyester elastomers are divided, according to the chemical structure of their elastic segment, into two types. Namely, one is a polyester-polyester type in which the elastic segment comprises an aliphatic polyester componet that is elasticer and has a lower glass transition temperature, and the other is a polyester-polyether type in which the elastic segment comprises an aliphatic polyether component.

as the thermoplastic polyurethane elastomer used in Comparative Example 2, and which is of polyurethane elastomer usable for a medical material.

The effects of the abovementioned embodiments will be described.

(1) If the hardness of a catheter material is Shore D of less than 50, it is impossible to ensure the firmness required for the catheter 12. According to the abovementioned examples, namely, an excellent inserting operability can be ensured, because the hardness of a catheter material is Shore D of over 50, thereby ensuring the firmness required for the catheter 12.

(2) If the impact resilience of a catheter material is less than 40 %, a catheter is easily plastically deformed, with its recovery reduced, and it is easily given same bend kink. According to the abovementioned examples, namely, an excellent indwelling stability can be ensured, because the impact resilience of a catheter material is over 40 % and it is satisfied, and a catheter hardly be, therefore, given any bend kink, and can smoothly follow the bend of a region where it will be indwelt, caused by the motion of an arm in its indwelling into a blood vessel.

(3) Since the impact resilience of a catheter material is satisfied as mentioned in the above item (2), an excellent removing operability can be ensured, because a catheter hardly be given any bend kink, and the bend kink given to the catheter in the indwelling stage can be immediately straightened when it is removed from a blood vessel, and as a result, the catheter can be smoothly removed from a region where it has been indwelt.

(4) Since the hardness of a catheter material is Shore D of below 70 and it is sufficiently flexible, an excellent biocompatibility can be ensured, because only a small stimulation will be given on a blood vessel wall when a catheter is indwelt into a blood vessel so that any damage of the blood vessel wall or phlebitis may not be caused.

(5) Since a catheter material is polyester elastomer, an excellent inserting operability can be ensured, because the anti-kink property is satisfied and a catheter 12 may not be, therefore, broken when it is inserted into a blood vessel.

(6) Since the anti-kink property of a catheter material is satisfied as mentioned in the above item (5), an excellent indwelling stability can be ensured, because a catheter 12 may not be broken even by the strong bend of a region where it will be indwelt, caused by the motion of an arm in its indwelling into a blood vessel.

(7) Since a catheter material is polyester elastomer, the catheter 10 exhibit a better anti-thrombus property, and has further a "biocompatibly" indwelling stability.

One of the preferred embodiments according to the present invention can be given which uses a polyester elastomer containing a contrast medium blended therein in the catheter portion of an indwelling catheter (at 12 of Fig. 1). If the untransmissibility of X-ray is given to a catheter portion, namely, the relative position of said catheter can be revealed through the fluoroscopy on a display device, or photographed on a X-ray film, by applying X-ray to a patient body or the like.

As to the contrast mediums to be blended in polyester elastomer, in addition, there can be typically given barium sulfate, bismuth trioxide, and bismuth subcarbonates and tungsten. The blending quantity of these contrast mediums to polyester elastomer is usually 5~ 50wt% in total, preferably 8 ~ 45wt%, and in particular most preferably 10 ~ 40wt%.

In a general embodiment, a contrast medium is blended so as to be uniformly dispersed in a catheter. According to the purpose, however, it may be unevenly dispersed positively. For a concrete example, there will be given such an embodiment that a contrast medium is blended so that one straight stripe or a stripe-pattern containing a plurality of stripes coaxially arranged is formed on a tube.

According to the pressent invention, as mentioned above, an indwelling catheter can be obtained which is excellent in the inserting operability, removing operability, indwelling stability, and biocompatibility.

4. An indwelling catheter, as set forth in claim 2, wherein said polyester elastomer is provided with a hard segment comprising an aromatic crystalline polyester and a elastic segment comprising an aliphatic polyether.

Fig. 1

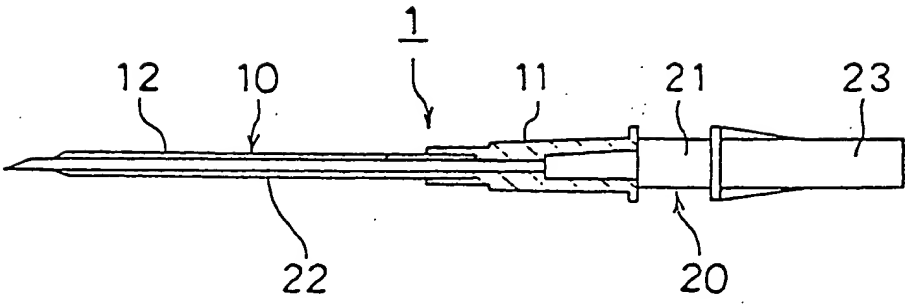
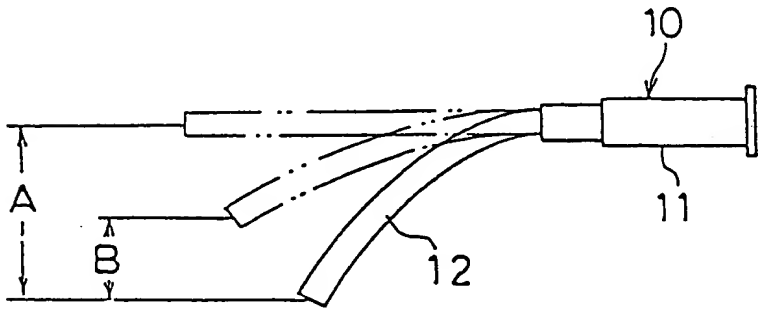


Fig. 2



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 40 1272

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 354 695 (BAXTER INTERNATIONAL) * column 4, line 27 - line 53 *	1-2	A61L29/00
X	FR-A-2 651 681 (MEDICORP RESEARCH LABORATOIRES CORP.) * page 1, line 19 - line 22 * * page 1, line 35 - page 2, line 12 *	1-2	
X	PLASTIQUES MODERNES ET ELASTOMERES vol. 36, no. 7, September 1984, PARIS, FRANCE pages 40 - 42; MARIE-HELENE TEXIER: 'LES PEBA A L'HEURE DE LA MATURITE' * page 41, last paragraph - page 42, paragraph 1; figures *	1-2	
A	EP-A-0 295 055 (YISSUM RESEARCH DEVELOPMENT CO.) * claims 1-8 *	1-4	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61M
A61L

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	16 JANUARY 1992	MIR Y GUILLEN V.

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